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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	034298-122	8436

7590 03/31/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/6/03, 1/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed03/06/2003; and IDS and amendment, both filed 01/21/2004.

Claims 1-17 are included in the prosecution.

Specification

The use of the trademark "Actifoam™" and "Gelfoam" have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants did not capitalize the trademarks in the specification.

Claim Rejections - 35 USC § 102

(A) Claims 1-6, 8-13, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2002/0042378 ('378) with the effective filing date of June 10, 1999.

The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of the wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. The wetting agent is impregnated with (claim 2) or mixed with (claim 3) or coated on (claim 4) the gelatin. Claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration, i.e. prior to use, by mixing (claim 6), or coating the wetting agent into the gelatin (claim 8). The composition is bioabsorbable (claim 9). The composition further comprises : growth factor, thrombus enhancing agents or antimicrobial agents (claim 10). The wetting agent forms 0.1 to 10% of the gelatin (claim 11). Claim 12 recites the coating achieved by applying to the surface of the gelatin a solution consisting of the wetting agent and solvent in a concentration of 1-20%, then the solvent removed by evaporation of the solvent (claim 13). The composition is in form of sterilized and packaged sponge (claim 15).

PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue subject to bleeding (page 2: 0012; page 5: 0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2: 0016). The most preferred cross-linked polymer is gelatin (page 3: 0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the

first full paragraph of page 9 of the instant specification as wetting agents. The non cross-linked polymer solublizes when exposed to blood and releases the cross-linked polymer so that it can hydrate as it absorbs water from the blood, that reads on the intended function of the wetting agent (page 1: 0012). Decreasing the hydration time of the cross-linked gelatin that claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration. The cross-linked gelatin particles are dispersed in a solution comprising non cross-linked polymer and the polyethylene glycol and well mixed before drying as recited in claims 3 and 6; that also reads on impregnating the wetting agent with gelatin because the gelatin particles are suspended in the wetting agent as in claim 2; and reads on coating the wetting agent on the surface of gelatin because the particles of gelatin are surrounded by the suspension of the wetting agents as claimed in claims 4 and 8; and example 2 shows that the dispersion of the cross-linked and non cross-linked polymers and plasticizer is performed prior to the formation of the sponge, i.e. prior to foaming (page 1:0012; page 2: 0018; page 4: 0035; page 6: 0045). The cross-linked polymers are degradable, i.e. bioabsorbable as claimed in claim 9 (page2: 0013). The composition further comprising bioactive agents including blood clotting agents such as thrombin, antibiotics, bacteriostatic and bacteriocidal agents, and antiviral, that reads on claim 10 (page 2: 0012; page 4: 0036). Example 2 of the reference shows that the amount of cross-linked gelatin in the composition is 1-4 grams, and the amount of polyethylene glycol is 0.1-2%, therefor, if the dispersion comprises 2 gm of gelatin that

is to be 2000 mg in 100 ml and 1% of polyethylene glycol that is 100 mg per 100 ml, then the amount of polyethylene glycol is calculated to form 5 wt.% of the cross-linked gelatin, reads on the amount claimed in claim 11 (example 2: pages 5-6). The method of making the material of the reference includes dispersing the cross-linked gelatin particles in a solution comprising polyethylene glycol (wetting agents) in a concentration of 0.1-2% and well mixing the suspension before drying, i.e. before evaporating the solvent as in claims 12 and 13 (page 3: 0021; page 4: 0035; page 6: 0045).). The composition of the reference can be in the form of sponge (page 4: 0035) that is provided in sterile packs, as claimed in claim 15 (page 3: 0020).

The limitation of claims 1-6, 8-13 and 15 are met by PGPB '378.

Response to Arguments

Applicants traverse the above rejection by arguing that the wetting agent of the present invention is incorporated with the gelatin to permits uniform wetting of the sponge and to facilitate the hydration of the sponge, while the reference disclosed non-cross-linked polymer that acts as binder.

Applicant's arguments above have been fully considered but they are not persuasive. The claims are directed to composition, and all the elements of the composition are disclosed by the reference. The wetting agents disclosed by applicants are the same agents disclosed by the reference under the non-cross-linked polymer. In any events, applicants are not claiming any specific wetting agents. In response to

applicant's argument that the reference does not disclose that the wetting agent to permit the uniform wetting of the sponge and to facilitate its hydration, the examiner position is that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

(B) Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2003/0088271 ('271).

PGPB '271 disclosed a kit form for delivery of absorbable sponge material to the puncture site to achieve hemostasis (page 2 and 3: 0058). The kit comprises absorbable sponge material in the form of pledget that is illustrated by number 40 in the drawings, and a syringe that is illustrated by number 50 of the drawings (see figures 3-5 in particular). The pledget gets hydrated in chamber 34, that means that the pledget is present in the kit as non-hydrated, (page 3: 0068, 0069; figures 3-5;). Thus, the kit comprises a syringe and non-hydrated pledget. The pledget consisting of cross-linked gelatin and can be pre-soaked with a beneficial agent, reads on wetting agent (page 5: 0083; page 10: 0137). The reference further disclosed the pledget provided with rapidly dissolved tip made of biocompatible, non-toxic, and non-immunogenic polymers such as

polyvinyl pyrrolidone, polyethylene oxide, and carbowax, and this also reads on pledget consisting of cross-linked gelatin and wetting agent as claimed in claim 16 (page 10: 0141).

The limitation of claim 16 is met by PGPB '271.

With regard to the rejection of the claim 16 under 35 U.S.C. 102(e) as being anticipated by PGPB '271, applicant has failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Claim Rejections - 35 USC § 103

Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPB '378.

The teaching of the PGPB '378 is discussed under 102 rejection above.

However, the reference does not teach impregnating the gelatin with the wetting agent as in claim 7, or the amount of the wetting agent in the gelatin composition after evaporation of the solvent.

It is expected that if the cross-linked gelatin is in the porous form, then the wetting agent is added to the porous material and mixed, the porous material will be impregnated with the wetting agent. Since applicant not claiming any particular form of

the cross-linked gelatin, thus, mixing would read on impregnated depending on the form of the gelatin used in the instant invention.

It is expected to one having ordinary skill in the art to adjust the drying and evaporation of the solvent in order to obtain the desired concentration of the wetting agent in the composition, and the claimed concentration of the wetting agent in claim 14 does not impart patentability to the claims, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to obtain a composition comprising cross-linked gelatin and wetting agent as disclosed by PGPB '378 and select the method of incorporating the wetting agent into the gelatin such as mixing, impregnating or coating depending on the form of the cross-linked gelatin, and adjust the degree of drying of the final product to achieve a desired concentration of the wetting agent in the composition, with reasonable expectation of success having a hemostatic composition that stop bleeding at the site of application within a reasonable time.

With regard to the rejection of claims 7 and 14 under 35 U.S.C. 103(a) as being unpatentable over PGPB '378, applicant has failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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